The Pharmacist Activist

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Editorial

A NEW YEAR, an OLD THEME

Can our National Pharmacy Associations Reach Nome?

The first part of the title for this editorial is not new. I used it as the title for my editorials in the January, 1996, January, 1998, and November, 1999 (substituting the word "millennium" for "year") issues of *Pharmacy Today* and the January, 2007 issue of *The Pharmacist Activist*. In the January, 1996 editorial, I voiced the opinion: "It is essential that we develop an organizational system with the size and strength to effectively address the challenges and threats to our professional roles and responsibilities and the issue of compensation for our services… The ideal would be to have a single national pharmacy organization with the size and strength provided by a large membership base, as well as a network of divisions or academies to provide strong, effective services and representation for each pharmacy practice area."

Thirteen years later, I hold the same opinion. The only thing that has changed is that I consider the need for action on this matter to be much more urgent now. We must identify and establish an organizational structure at the national level that will most effectively meet the needs, interests, and opportunities for the profession of pharmacy.

The second part of the title for this editorial requires some explanation. Two years ago I had the opportunity to speak at a meeting of the Alaska Pharmacists Association in Anchorage. The scheduling of the meeting coincided with the ceremonial start of the Iditarod Trail Sled Dog Race, an event that requires great determination and endurance in which each team of typically 16 sled dogs and its musher race for approximately 1,150 miles over nine or more days to the destination in Nome. The ceremonial start of the race was just several blocks from the meeting hotel and as I walked this short distance I was struck by the ever increasing noise level. As I reached the area in which the sled dog teams and mushers were gathered prior to the start of the event, I observed that the dogs in each of the teams were noisily barking and jumping and pulling in all different directions. For some reason I thought of our national pharmacy associations.

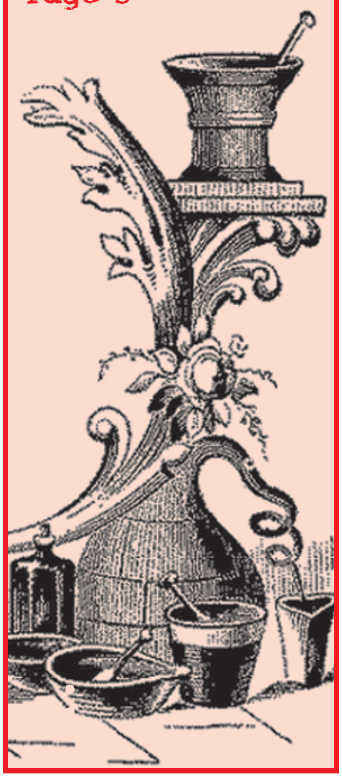
When the Iditarod officially begins, there is a very different scenario. The sled dogs with their musher work together as a team in the same direction and with the same purpose of reaching the destination in Nome. Unfortunately, at this time, a question exists as to whether our national pharmacy associations can work together for the good of the profession which is the basis for the existence of each of the associations. Unless there is more of a willingness to work together and make some compromises, our associations will not attain the goals that protect and advance the professional role of pharmacists. Or, in the context of the analogy, our national associations will not reach Nome.

Encouraging responses

Soon after the publication of my January 2007 editorial I heard from the executive vice presidents of two of the national pharmacy associations, as well as one of the elected presidents of a national association. I was informed that the Joint Commission of Pharmacy Practitioners (JCPP), comprised of 11 national pharmacy organizations, was discussing the organizational structure for pharmacy at the national level and that there was reason for optimism that these deliberations would provide encouraging results.

The very fact that members of the leadership of the national pharmacy associations meet periodically as the JCPP is encouraging. To its credit, the JCPP

Contents



has articulated the following "Future Vision of Pharmacy Practice":

"Pharmacists will be the health care professionals responsible for providing patient care that ensures optimal medication therapy outcomes."

An action plan for implementation has also been prepared that identifies three critical areas that are most important in achieving the vision: Practice Model, Payment Policy, and Communications.

The development at the national level of a vision and implementation plan for the profession is very important. However, this is the easy part and it is a huge leap from these statements to successful implementation and positive outcomes. I would contend that the current organizational structure at the national level does not position the profession to be successful in achieving the vision stated above, and which I support.

Discouraging responses

After receiving the encouraging responses regarding the JCPP's consideration of the profession's organizational structure, I looked forward to hearing more specific recommendations and of actions that were being planned. However, aside from rumors about a "federation model" for the national associations, information has not been forthcoming. After waiting for approximately two years from the time I was provided the encouraging responses, I started to ask questions of some of the individuals who participated in the discussions. Their comments now were anything but encouraging. Indeed, they were downright discouraging. Consensus has not been attained and discussions of the topic may be at an impasse.

In my opinion, maintaining the "status quo" with respect to the profession's organizational structure will not be sufficient to even maintain our current status, let alone move the profession forward to attain the vision articulated by the JCPP and the goals to which many pharmacists aspire. If the highest level leaders of our profession and our national associations have not been able to make progress through the JCPP discussions, they will have failed in the opportunity to successfully address a very difficult issue, but one that is as or more important than any other professional responsibility with which they have been entrusted as an association leader. At this time, it would not be productive to try to determine which individuals and associations are most responsible for the lack of progress regarding this matter. However, pharmacists must respond that an impasse in these discussions is not acceptable, and we must insist that the discussions be continued and that reports be provided to the memberships of the participating associations.

Some related issues require immediate attention

While efforts continue to identify and establish an organizational structure at the national level that will best serve the interests and needs of the profession, there are also other important matters that can be addressed concurrently:

1. Many state and local pharmacy associations have serious financial and staffing problems and some are no longer active. The national associations must provide more extensive and stronger support to help maintain the viability and effectiveness of the associations at all levels.

2. The national associations must commit more extensive resources and personnel to achieve stronger political influence. Notwithstanding some successes with certain legislative initiatives, our overall influence as a profession has been weak and fragmented. The following is one of many examples in which the national associations may achieve synergies and efficiencies through a better organizational structure. Why should it be necessary for each large national association to have its own political action committee (PAC)? There could be just one PAC that is much better funded and has greater political influence. The individuals on the Board of Directors of the single large PAC would be from the participating associations in a number consistent with the contributions from the membership of their particular association. Similarly, the legislators and legislative issues supported financially by the PAC would reflect the level of contributions from the individual associations.

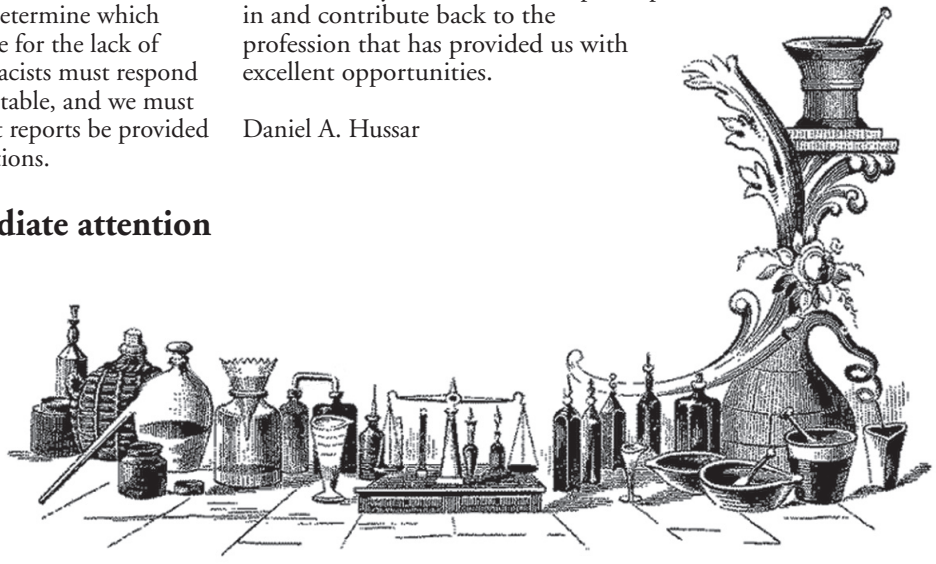
3. Pharmacists employed in chain pharmacies are the largest group of practicing pharmacists. However, this is also the group that, on a percentage basis, has the lowest membership and involvement in pharmacy associations. The pertinent associations must develop effective strategies to communicate with chain pharmacists and attract their membership.

4. The national associations must be far more active in challenging and criticizing activities and programs that are insulting and demeaning to pharmacists and our profession (e.g., kickback arrangements, industry influence on educational programs, free prescriptions for generic antibiotics, $4 generic prescriptions).

Responsibility of individual pharmacists

Although the focus of this editorial has been on the national associations, I would be remiss if I did not also identify the responsibilities we have as individual pharmacists. I have not done enough personally to address the issues about which I have concern and the same is true for most other pharmacists. At the same time we insist on more and better efforts from our professional associations, we must accept responsibility and accountability as individuals to participate in and contribute back to the profession that has provided us with excellent opportunities.

Daniel A. Hussar



New Drug Review

Fesoterodine fumarate (Toviaz – Pfizer)

Agent for Overactive Bladder

New Drug Comparison Rating (NDCR) = 3

(no or minor advantages/ disadvantages)

in a scale of 1 to 5, with 5 being the highest rating

Indication:

Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.

Comparable drug:

Tolterodine extended-release (Detrol LA).

Advantages:

- Use in an 8 mg once-a-day dosage has been reported to be more effective than tolterodine extended release in a 4 mg once-a-day dosage;
- Appears to be less likely to prolong the QT interval of the electrocardiogram.

Disadvantages:

- Use in an 8 mg once-a-day dosage has been reported to cause a higher incidence of adverse events (e.g., dry mouth) than tolterodine extended release in a 4 mg once-a-day dosage;
- Not recommended for use in patients with severe hepatic impairment (tolterodine may be used in a lower dosage).

Most important risks/adverse events:

Contraindicated in patients with urinary retention, gastric retention, or uncontrolled narrow-angle glaucoma; not recommended for use in patients with severe hepatic impairment; must be used with caution in patients with bladder outlet obstruction, decreased gastrointestinal motility (e.g., those with severe constipation), myasthenia gravis, or controlled narrow-angle glaucoma; action may be increased in patients taking a potent CYP3A4 inhibitor (e.g., clarithromycin [e.g., Biaxin]) concurrently, and in patients with severe renal impairment.

Most common adverse events (and the incidences in patients receiving 8 mg once-a-day and 4 mg once-a-day, respectively):

Dry mouth (35%; 19%), constipation (6%; 4%), dry eyes (4%; 1%), dyspepsia (2%; 2%).

(Continued on Page 4)

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New Drug Review (cont.)

Usual dosage:

4 mg once a day, initially; may be increased to 8 mg once a day based on individual response and tolerability; daily dosage should not exceed 4 mg in patients with severe renal impairment or who are taking a potent CYP3A4 inhibitor concurrently.

Products:

Extended-release tablets – 4 mg, 8 mg; tablets must not be chewed, divided, or crushed.

Comments:

Fesoterodine is the sixth muscarinic receptor antagonist to be approved for the treatment of overactive bladder, joining tolterodine (e.g., Detrol LA), oxybutynin (e.g., Ditropan XL), trospium (e.g., Sanctura XR), darifenacin (Enablex), and solifenacin (Vesicare). It is most closely related to tolterodine and both drugs are converted to the same active metabolite, 5-hydroxymethyl tolterodine. Following administration, fesoterodine is rapidly and extensively hydrolyzed to this active metabolite that is responsible for the antimuscarinic activity. Its effectiveness was demonstrated in two placebo-controlled studies, and the improvement of symptoms was greater with the use of a dosage of 8 mg once a day than with the dosage of 4 mg once a day. In a study in which fesoterodine was compared with tolterodine extended-release, fesoterodine has been reported to be significantly better than tolterodine in improving a number of endpoints; however, the dosage of fesoterodine was 8 mg once a day and the dosage of tolterodine was 4 mg once a day. Although the amounts of the parent compounds and the active metabolite cannot be exactly quantified, there is considerably more active drug in an 8 mg dose of fesoterodine than in a 4 mg dose of tolterodine. This is also reflected in the higher incidence of adverse events reported with fesoterodine in this study (e.g., a 34% incidence of dry mouth with the 8 mg dose of fesoterodine compared with a 17% incidence with the 4 mg dose of tolterodine).

The most commonly experienced adverse events with both fesoterodine and tolterodine are related to their anticholinergic activity. The labeling for tolterodine, but not that for fesoterodine, includes a precaution regarding prolongation of the QT interval of the electrocardiogram.

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